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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,652	09/29/2006	Jean-Hilaire Saurat	3493-0175PUS1	2767

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EXAMINER	
KARPINSKI, LUKE E	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
03/15/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,652	SAURAT ET AL.	
	Examiner	Art Unit	
	LUKE KARPINSKI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/23/2012 and 1/27/2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2 and 4-8* is/are pending in the application.

5a) Of the above claim(s) *5 and 7* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,4,6 and 8* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/28/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claims 1, 2, and 4-8 are pending.

Claims 5 and 7 are withdrawn.

Claims 1, 2, 4, 6, and 8 are under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over translation of JP 2000-344656 to Kurimura et al., as supplied by applicant, in view of USPN 6,193,956 to Liu et al. and USPN 4,303,676 to Balazs.

Applicant Claims

Applicant claims a topical composition comprising a hyaluronate fragment having a molecular weight of 50,000 to 750,000 and retinal.

Applicant further claims fragments having a molecular weight from 50,000-250,000 and 250,000-750-000, and methods of treating skin by application of said compositions.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kurimura et al. teach cosmetic formulations for application to the skin for treating skin roughness, which reads on wrinkled or dry skin (abstract), comprising hyaluronic acid having a molecular weight from 10,000-600,000 (claims and [5]), retinol acetate and vitamin A oil ([11] and examples).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Kurimura et al. do not teach hyaluronate. This deficiency in Kurimura et al. is cured by Balazs. Balazs teaches that either hyaluronic acid or sodium hyaluronate may be used as a skin moisturizer (col. 1). It is noted that Liu et al. also teach hyaluronic acid (col. 10, line 25) and hyaluronate (example 28).

Further, Kurimura et al. do not teach retinal. This deficiency is cured by Liu et al. Liu et al. teach topical skin care formulations comprising functionally equivalent retinoids including retinal and retinol acetate (col. 1, line 43 to col. 2, line 10). Functional equivalency of retinal and retinol acetate is also evidenced by US 2002/0114819 to Tashiro et al. [13].

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the use of hyaluronate, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of

Kurimura et al. with hyaluronate as taught by both Balazs and Liu et al. in order to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because all references teach topical skin care formulations, Kurimura et al. teach the use of hyaluronic acid and Balazs and Liu et al. teach that hyaluronic acid and hyaluronate both act to moisturize the skin. Therefore it would have been obvious to utilize the hyaluronate of Balazs and Liu et al., in the formulations of Kurimura et al. in order to use a functionally equivalent moisturizer.

Regarding the use of retinal, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Kurimura et al. with retinal as taught by Balazs in order to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because both references teach topical skin care formulations, Kurimura et al. teach retinol acetate and Liu et al. teach that retinal and retinol acetate are functional equivalents. This fact is also evidenced by Tashiro et al. Therefore it would have been obvious to utilize the retinal of Liu et al., in the formulations of Kurimura et al. in order to use a functional equivalent of retinol acetate.

Regarding limitations to method steps all references teach topical application for skin treatment which reads on the method steps.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 1, 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,193,956 to Liu et al. in view of USPN 4,303,676 to Balazs.

Applicant Claims

Applicant claims are delineated above and incorporated herein.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Liu et al. teach topical compositions comprising retinal (col. 3, lines 18-32 and col. 10, lines 23-28), that retinoids are suggested for treating wrinkles and dryness of the skin (col. 1, lines 43-49), said compositions further comprising hyaluronic acid (col. 10, lines 19-28) and that hyaluronic acid provides moisturizing benefits and aids in treating wrinkles (col. 10, lines 23-28 and col. 11, lines 11-14).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Liu et al. do not teach molecular weights of said hyaluronic acids. This deficiency in Liu et al. is cured by Balazs. Balazs teaches moisturizing skin care compositions comprising more than one hyaluronate fraction, one having lower MW at 10,000 to about 200,000 Da and one having a higher MW at 1-4.5 million Da and that lower

molecular weight penetrates deeper into the tissue while higher molecular weight will not penetrate as far (col. 1, lines 59-67 and col. 2, line 59 to col. 3, line 2). Balazs also teaches that said lower MW fractions are produced through heat treatment of higher (1,000,000 - 4,500,000 Da) MW fractions and gives time and temperature parameters for said mw reduction (col. 2).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the limitation of molecular weight, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Liu et al. with more than one hyaluronate fragment having different molecular weights, one between 50,000 and 750,000 and another between 250,000 and 750,000 as taught by Balazs in order to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Liu et al. teach hyaluronic acid used in topical skin care compositions used for moisturizing purposes and Balazs teaches hyaluronic acid and hyaluronate used in moisturizing skin care compositions and molecular weight ranges to use as well as the fact that different mw ranges will penetrate to different skin layers. Therefore it would have been obvious to utilize the 1-4.5 million Da hyaluronate molecular weights of Balazs and to modify said fragments into the desired number of different MW fractions, including one between 50,000 and 250,000 and one between 250,000 and 750,000, in order to moisturize the skin at different layers in order to produce moisturizing compositions using hyaluronate

fractions with known molecular weight ranges to penetrate to different depths in the skin.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 1/23/2012 have been fully considered but they are not persuasive.

Applicant argues that the declaration provided by Dr. Kaya on 1/27/2012 demonstrates that a hyaluronate (HA) fragment of 50-750 kDa provides unexpected results when combined with retinal over lower and higher molecular weight fractions and that said declaration cures the alleged deficiencies in the declaration filed by Dr. Saurat on 5/10/2011.

This argument is not found persuasive because the deficiency in both declarations is that the experiments shown are not a side by side comparison with the closest prior art. Barnes et al. teaches compositions comprising retinal and hyaluronate fragments having a molecular weight range of 50,000 to 400,000 while the instant claims recite a range from 50,000-750,000, from 50,000 to 250,000, and from 250,000 to 750,000. The declarant attempts to remedy this by providing the logic that "The

experiments with hyaluronate fragments of 50,000-750,000 should certainly reveal similar results". However, applicant has provided no data for any of the claimed ranges.

Further, the results pointed to in Barnes et al. are not synergistic. At best, said results are additive or a difference in degree. There is no evidence of synergy and applicant has provided no rational for synergy, therefore the obviousness rejection has not been overcome with a showing of unexpected results.

Applicant further argues that the declaration provided by Dr. Kaya provides evidence that the in vivo effects on humans would be expected by one skilled in the art to be the same as in vitro effects on mouse skin.

This argument is found persuasive by the examiner.

Applicant also argues that a showing of synergy is not required to overcome and obviousness rejection, merely a showing of unexpected results

While this is true, it has no bearing on the instant analysis of the declaration because the results provided by applicant are not a side by side comparison with the closest prior art and said results are expected

Applicant further argues that "the data shows that RAL + HAF has a statistically significant improved and unexpected activity when compared to HAF + other retinoid. Thus RAL + HAF possess unexpected properties".

This argument is not found persuasive because Kurimura et al. teach a fragment of 10-600 kDa, which significantly overlaps the claimed range of 50-750 kDa. Applicant may provide a side by side comparison with Kurimura et al., which is the closest prior art. Applicant's showing of results for fractions of 50-750 kDa vs. 30-50 kDa and 1000-

1250 kDA does not overcome the 10-600 kDa range of Kurimura et al. It is further noted by the examiner that based on the results provided the addition of a retinal provides no unexpected results, as the increase due to the addition of retinal is merely an expected additive effect.

Declaration/Affidavit

The declaration under 37 CFR 1.132 filed 1/27/2012 is insufficient to overcome the rejection of claims 1, 2, 4, 6, and 8 based upon the obviousness rejection as set forth in the last Office action.

The declaration provided by Dr. Kaya on 1/27/2012 provides a showing that HA fragments of 50-750 kDa, when combined with retinal, provide an unexpected benefit over fractions of 30-50 kDa and 1000-1250 kDa. This showing is not sufficient in that said experiments are not a side by side comparison with the Kurimura et al. fractions of 10-600 kDa. Further, said fractions combined with retinal do not provide any showing of unexpected results or synergy. The combination merely provides an expected additive increase.

The examiner suggests that an interview is held to discuss the art and rejections of record as well as all declarations that have been filed. Applicant is encouraged to call the examiner and schedule said interview prior to a response to the instant action being filed.

Conclusion

Claims 1, 2, 4, 6, and 8 are rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on monday-friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616